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March 16, 1999

Dockets Management Branch (HFA -305) Food and Drug Administration 7500 Standish Place Rockville, MD 20855

Re: Docket Number 98B00182 (4-AMINOPRYIDINE)

To Whom It May Concern:

Multiple Sclerosis (MS) is a disease that randomly attacks your nervous system, wearing away the control you have over your body. Symptoms may range from numbness to paralysis and fatigue to blindness. MS is a devastating disease because it is so unpredictable. A dear friend of mine was diagnosed with MS in December of 1995. He has been able to "manage" his illness by using several drugs besides altering his lifestyle. One drug which enables him to continue working and be a contributing member of society is 4-Aminopryadine (4-AP). He takes this drug three times a day. The only way this drug is available is through a compounding pharmacy (ie, they actually make the capsules in the appropriate dosage). A pharmaceutical company has not marketed this drug and thus does not have a strong lobbying audience. It is vital to his health that access to this drug is maintained.

Due to the Food and Drug Modernization Act of 1997, signed into Public Law 105-77, November 21, 1997, the referenced drug, 4-Aminopyridine, may very soon be unavailable. I understand that you are still considering placing 4-AAP on the permanent list of approved compounded drugs. I urge you to include this drug on the list. The benefits from 4-AP in the last three years have far outweighed any side effects he has experienced during that time. If 4-Aminopryadine is NOT on the compounding drug list, getting 4-AP anywhere after your effective ruling will be IMPOSSIBLE.

Thank you for your attention to this matter.

Sincerely,

Wayne B. Mahy

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